APPLICATION OF HACCP PRINCIPLES FOR THE MEAT INDUSTRY

GUIDANCE SHEET NO: 18

VALIDATION
INTRODUCTION TO PRINCIPLE 6 & VALIDATION

INDRODUCTION TO PRINCIPLE 6 "VERIFICATION"

Principle 6 "Verification" is the principle which confirms that the HACCP plan if followed will produce safe food for the final consumer. The process of verification has three key components:

(1) Validation – "Will the HACCP plan ensure that safe food will be produced?"

(2) Verification – "Is the HACCP plan working, is it producing safe food?"

(3) Review (Maintenance of the HACCP system) - "Is the HACCP plan up to date?"

Part 1: Validation is discussed in this guidance sheet. Verification and Review of the HACCP system are discussed in guidance sheets 19 & 21.

WHEN SHOULD I CARRY OUT THE DIFFERENT STEPS OF PRINCIPLE 6?

The three steps of principle 6 are carried out at different times and serve different purposes as follows:

(1) Validation – "Will the HACCP plan ensure that safe food will be produced?" Validation must be done before the HACCP system is put into operation in the factory.

(2) Verification – "Is the HACCP plan working, is it producing safe food?" Verification is carried out periodically (time interval varies according to the severity of the potential food safety risks).

(3) Review (Maintenance of the HACCP system) - "Is the HACCP plan up to date?" Reviews are made at least annually and must be made if something in the system is changed such as an operational parameter (temperature, time etc), product formulation or supplier.

VALIDATION OF THE HACCP SYSTEM (PART 1 OF PRINCIPLE 6)

Validation is the process by which you collect evidence to prove that:

(1) All of the judgements and assumptions that you have made to identify and evaluate relevant hazards, identify controls, correctly select critical control points, establish effective monitoring and corrective action procedures are all based on scientific evidence. **"The theory of the HACCP system is correct"**

(2) That the HACCP system delivers the required level of control of food safety risks in practice. **"The HACCP system works in practice"**

STARTING THE PROCESS OF VALIDATION

You need to decide:

- What validation checks are to be performed and when they will made?
- Who will be responsible for carrying them out?
- What information is to be recorded, where and by whom and
- Who will check that validation and verification has been carried out properly and where and how this check is to be recorded (the validation should be conducted using checklists supplied as part of the CAREC Safe Processing System, a manager/supervisor should check the validation report and sign off report as correct)?
- Do you have sufficient capacity inhouse to complete the validation process successfully or do you need to bring in external expertise?

The last point is very important, if your inhouse expertise is insufficient there is a risk that management will put reliance in a system that does not manage food safety effectively. In extreme cases this could result in the death of some of your customers.

VALIDATION CHECKS

To validate the accuracy and completeness of the plan, check:

- The scope of the HACCP plan
- Technical data
- Process flow diagram
- Hazard analysis
- Effectiveness of control measures (hygiene practices such as cleaning, training) in eliminating food safety hazards or controlling them to an acceptable level.
- That control point identification, critical / legal limits, monitoring and corrective action plans are appropriate and effective.

It is recommended that, after the team has carried out its own validation checks, an independent expert is involved to provide an objective view.

SCIENTIFIC VALIDATION

Production may involve complex technical issues, such as the chilling of large quantities of meat, heat treatments, smoking or fermentation where time / temperature or other parameters must be established and applied accurately to achieve a safe result.

To confirm that the operation is safe it may be enough to apply relevant legal limits or refer to industry guides to manufacturing or to scientific publications. Where the procedure or product is unusual, it may be necessary to get specialist scientific advice.

If the manufacturer wishes to use different processing parameters from those given in industry standard guidance, the safety of the alternative parameters will have to be demonstrated and recorded.

RECOMMENDED FORMAT FOR VALIDATION STUDIES

Validation studies should include the following:

1. Identification of hazards:
- You should reference an authority (scientific-journal, industry-guidance, textbook etc) for each identified hazard
- Or record the reasoning of the HACCP team for the inclusion of each hazard in the HACCP plan.

2. Evaluation of hazards:
- You should include a written justification for the hazard evaluation process used to identify significant hazards in Principle 1
- An explanation of why a given hazard has been discounted should be included.

3. Selection of critical control points:
- You should specify the method used to select critical control points. For example, use of the Codex Alimentarius Commission decision tree.

4. Define Critical Limits:
- Critical limits can often be validated by reference to relevant literature such as legislation or industry guides.
- If such critical limits are selected then you must demonstrate that your process is capable of operating at the proposed critical limits.
- If there is no published evidence that proposed critical limits will be sufficient to achieve control at a CCP, it will be necessary to conduct suitable validation exercises such as mathematical and/or microbiological modelling supported by challenge testing or other relevant studies.

5. Establish Corrective Actions:
- Where a corrective action includes an option to rework or reuse a non-conforming product, evidence must be provided to guarantee that such reuse will result in safe food.

DEMONSTRATING THAT FOOD SAFETY RISKS ARE CONTROLLED – CASE STUDY: VACUUM PACKED COOKED HAM

In cooked vacuum-packed meats there is a risk of survival and growth of spores of *Clostridium botulinum*. This organism produces a deadly toxin called botulin.

Various strategies exist for prevention of this risk in vacuum packed cooked meat but the most effective is to use the correct combination of temperature and time during the cooking part of the process.

The Food Standards Agency (FSA) of the United Kingdom has published science-based guidance on correct temperature and time combinations for destruction of *C.botulinum* spores in vacuum packed meats such as hams.

The recommended value is for the core temperature of the meat to be held at a minimum of 90°C for at least 10 minutes (see table at the end of this guidance sheet). This value would be taken as the critical limit for the critical control point covering cooking of the vacuum-packed hams. A safety margin of 25% would be added to the time factor giving a target value of 90°C for 13 minutes.

The time taken for the core of the meat to reach the required temperature will vary with batch size. The manufacturer needs to determine the total process time required for safe cooking of a given mass of product. This must be demonstrated experimentally and records kept of the data collection process.

Temperature probes must be inserted into the centre of the batch of meat to measure the core temperature. The total time taken for the batch to reach 90°C plus cooking time must be recorded. This process must be repeated several times to obtain enough values to be sure that the cooking process will be consistent and reliable.

If the values of the critical limit are changed the validation process must be repeated to generate a new set of critical limit values.

APPROVED TEMPERATURE/TIME COMBINATIONS FOR VACUUM PACKED MEAT

Table of approved combinations of temperature and time (critical limits) for control of *Clostridium botulinum* in vacuum packed cooked meats

°C	Minutes	°C	Minutes	°C	Minutes
80	129	87	22	94	4
81	100	88	17	95	3.2
82	77	89	13	96	2.5
83	60	**90**	**10**	97	2
84	46	91	7.9	98	1.6
85	36	92	6.7	99	1.3
86	28	93	5	100	1

Adapted from: The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*. Food Standards Agency, United Kingdom (December 2020).

DO NOT forget that A safety margin of 25% must be added to the time factors given in the table above to generate target values for use in the factory